Request for permission for pharmaceutical industry oral testimony at Idaho Medicaid's P&T Committee meeting on 5-20-2016.

Submission # 4

As of May 5, 2016, this submission has not been accepted for oral presentation at the meeting.

Gennrich, Jane - Medicaid

From: Medical Services Mailbox <Medical_Services@pharma.com>
Sent: Tuesday, April 12, 2016 4:17 PM
To: Eide, Tamara J. - Medicaid
Subject: Information Regarding Butrans® (buprenorphine) Transdermal System
Attachments: Purdue Medical Services Response 216390.PDF; Butrans FPI.pdf

Dear Dr. Eide:

The following information regarding Butrans® (buprenorphine) Transdermal System is being submitted in response to the Idaho Medicaid call for new scientific information for the upcoming Pharmacy and Therapeutics Committee meeting scheduled for May 20, 2016 that will include a review of long-acting narcotic analgesics.

If you have any further questions please call us at 888-726-7535 and select option #1.

Sincerely,

Purdue Medical Services

PURDUE

Purdue Pharma L.P.

One Stamford Forum
Stamford, CT 06901-3431
www.purduepharma.com

April 12, 2016

Tami Eide, PharmD
Idaho Medicaid
Pharmacy & Therapeutics Committee
3232 Elder Street
Boise, ID 83705

Dear Dr. Eide:

The following information regarding Butrans® (buprenorphine) Transdermal System is being submitted in response to the Idaho Medicaid call for new scientific information for the upcoming Pharmacy and Therapeutics Committee meeting scheduled for May 20, 2016 that will include a review of long-acting narcotic analgesics.

Background

Butrans is a CIII, seven-day transdermal formulation of buprenorphine indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risk of overdose and death with extended-release opioid formulations, reserve Butrans for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Butrans is not indicated as an as-needed (prn) analgesic.[1]

The Butrans Full Prescribing Information (FPI) includes a Boxed Warning describing the risk of addiction, abuse, and misuse, the risk of life-threatening respiratory depression, and the risk of accidental exposure and neonatal opioid withdrawal syndrome.[1] The most common adverse reactions (≥5%) reported by patients treated with Butrans in clinical trials were nausea, headache, application site pruritus, dizziness, constipation, somnolence, vomiting, application site erythema, dry mouth, and application site rash.[1] Please review the Butrans FPI provided as an attachment and also available at www.Butrans.com.

While the FDA approved indication and boxed warning for Butrans may be similar to, or the same as, other extended-release opioids, there are some distinct differences in terms of appropriate patient selection for Butrans therapy.

- Butrans is the only CIII transdermal extended-release opioid medication. As a CIII opioid, prescriptions may be called in or faxed to the pharmacy and prescribed with refills.

- Butrans is the only extended-release opioid that provides 7 days of buprenorphine delivery.
- Butrans has demonstrated efficacy and is the only transdermal opioid approved for both opioid-naïve patients and opioid-experienced patients requiring up to 80 mg/day of oral morphine equivalents (e.g., up to 40 mg/day of oral oxycodone or hydrocodone).[1-3]
    - Butrans 5 mcg/hour is the starting dose in appropriate opioid-naïve patients.
    - Based on the patient's current opioid dose, Butrans 5 or 10 mcg/hour is the starting dose in appropriate opioid-experienced patients.
    - Butrans can be titrated every 72 hours, if needed, to a dose that provides adequate analgesia and minimizes adverse reactions.
    - The highest dosage of Butrans 20 mcg/hour may not provide adequate analgesia for patients requiring greater than 80 mg/day of oral morphine equivalents (e.g., >40 mg/day of oral oxycodone or hydrocodone). Do not exceed a dose of one 20 mcg/hour Butrans system due to the risk of QTc interval prolongation.[1]

Place in Therapy

Purdue recommends allowing access to Butrans, a CIII product with a maximum recommended dose of 20 mcg/hour, for use by appropriate patients who require up to 80 mg/day of oral morphine equivalents. If Idaho Medicaid believes establishing prior authorization criteria for Butrans is necessary, we ask that you consider Butrans for use in patients who require up to 80 mg/day of oral morphine equivalents and have tried an immediate-release opioid or tramadol.

Recent Publication

As Idaho Medicaid is requesting only new comparative scientific information/publications within the last year (or last DERP review), cited for your review is a published study evaluating the effectiveness and safety of transdermal buprenorphine versus sustained-release tramadol in patients with moderate to severe musculoskeletal pain.[4]

If we can be of further assistance, please contact Purdue Medical Services at 1-888-726-7535, prompt #1.

Sincerely,

Marc Cataldo, PharmD
Director, Medical Services

nc/NC/216390

References:

1. Butrans [Full Prescribing Information]. Stamford, CT: Purdue Pharma L.P.

2. Steiner D, Munera C, Hale M, Ripa S, Landau C. Efficacy and safety of buprenorphine transdermal system (BTDS) for chronic moderate to severe low back pain: a randomized, double-blind study. *J Pain.* 2011;12(11):1163-1173.
3. Steiner DJ, Sitar S, Wen W, et al. Efficacy and safety of the seven-day buprenorphine transdermal system in opioid-naïve patients with moderate to severe chronic low back pain: an enriched, randomized, double-blind, placebo-controlled study. *J Pain Symptom Manage.* 2011;42(6):903-917.
4. Leng X, Li Z, Lv H, et al. Effectiveness and safety of transdermal buprenorphine versus sustained-release tramadol in patients with moderate to severe musculoskeletal pain: an 8-week, randomized, double-blind, double-dummy, multicenter, active-controlled, noninferiority study. *Clin J Pain.* 2015;31:612-620.

Enclosure:
Reference 1.